

SUBMITTED BY:

**STEPHEN M. LANIER, PH.D.
VICE PRESIDENT FOR RESEARCH**

**REPORT ON WAIVERS APPROVED
TO BOARD STATUTE 2.41.01.140**

BACKGROUND

Three research projects required a petition to waive Statute 2.41.01.140 because of review restrictions on publishing the research results. These waivers have been approved by the Vice President for Research to allow acceptance of the relevant grant or contract, acting in accordance with the University's research policy on restricted and proprietary research.

OVERVIEW

VERTEX PHARMACEUTICALS INCORPORATED

This waiver allowed acceptance of a clinical trial funded by Vertex Pharmaceuticals Incorporated. The project, "A Phase 1/2 Study of VX-445 in Healthy Subjects and Subjects with Cystic Fibrosis," is led by Dana Kissner, M.D., associate professor – clinical, Department of Internal Medicine, School of Medicine. The project will evaluate the safety, tolerability and efficacy of VX-445 in triple combination with two other drugs (Tezacaftor (TEZ) and Ivacaftor (IVA)) in subjects who are 18 years of age or older with Cystic Fibrosis. The study will also evaluate the pharmacokinetics of VX-445 when administered in triple combination with TEZ and IVA. If this combination of drugs is found to be safe and effective, it will be a new treatment for Cystic Fibrosis. This project required a waiver to Board Statute 2.41.01.140 because the sponsor requires that all resulting publication submissions and presentations are delayed up to 120 days in order to protect the potential patentability of any technology. The total anticipated funding on this project is \$157,940.

LEONARD-MERON BIOSCIENCES, INC.

This waiver allowed acceptance of a clinical trial study funded by Leonard-Meron Biosciences, Inc. The project, "A Phase 3, Multi-Center, Randomized, Double-Blind Study to Evaluate the Efficacy and Safety of Mino-Lok Therapy (MLT) in Combination with Systemic Antibiotics in the Treatment of Catheter -Related or Central Line-Associated Bloodstream Infection," is led by Pranatharthi H. Chandrasekar, M.D., professor, clinical educator and chief, Division of Infectious Diseases. The purpose of this study is to examine the effectiveness of an investigational drug in a patient having a catheter-related or central line associated bloodstream infection. The goal of the study is to see if the investigational drug makes it possible for the central venous catheter to not have to be replaced while treating a bloodstream infection with antibiotics. If this experiment is successful, it will avoid removal of infected vascular catheters that will improve quality of life for cancer patients. This project required a waiver to Board Statute 2.41.01.140

because the prime funding agency requires that all resulting publication submissions and presentations are delayed up to 120 days in order to protect the potential patentability of any technology. The total anticipated funding on this project is \$199,863.

LEAR CORPORATION

This waiver allowed acceptance of a project funded by Lear Corporation. The project, "Lear's Dynamic Safety Feature for Rear Impact Crashes: Driving Simulator Studies," is led by Randall Commissaris, Ph.D., associate professor of pharmaceutical science, Applebaum College of Pharmacy and & Health Sciences. The project will allow for research into determining the facts of activating a rear-end crash injury mitigation system on driver behavior and driving performance in a driving simulator. This project required a waiver to Board Statute 2.41.01.140 because the sponsor requires approval prior to allowing any publications as a result of this study. The total anticipated funding on this project is \$109,300.